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<b>IN RE PHARMACEUTICAL INDUSTRY</b>	)	<b>Master File No. 01-12257-PBS</b>
<b>AVERAGE WHOLESALE PRICE LITIGATION</b>	)	<b>Subcategory Case No. 06-11337</b>
<hr/>	)	
	)	<b>Judge Patti B. Saris</b>
<b>THIS DOCUMENT RELATES TO:</b>	)	
<i>State of California, ex rel. Ven-A-Care of the Florida</i>	)	<b>Magistrate Judge</b>
<i>Keys, Inc. v. Abbott Laboratories, Inc., et al.</i>	)	<b>Marianne B. Bowler</b>
Case No: 1:03-cv-11226-PBS	)	
	)	

Pursuant to Rule 56.1 of the Local Rules of this Court, Plaintiffs hereby submit their Response to Sandoz Inc.'s Statement of Undisputed Facts in Support of Sandoz Inc.'s Motion for Summary Judgment. Plaintiff also submits its own Statement of Additional Undisputed Material Facts in Opposition to the pending motion. In the responses that follow, any statement submitted by Sandoz that Plaintiffs do not dispute is undisputed solely for purposes of Plaintiffs' response to Sandoz's motion for summary judgment. Plaintiffs reserve the right to dispute any such statement of fact for purposes of trial. *See* LR 56.1.

1. The Medicaid program was signed into law in 1965 as part of Title XIX of the Social Security Act and is a joint federal-state program that provides medical assistance to financially needy patients. *See* 42 U.S.C.A. § 1396-1 (2009).

2. Pursuant to the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388 (1990), manufacturers of prescription drugs, including Sandoz, which seek to participate in the Medicaid program under Title XIX of the Social Security Act for provision of outpatient drugs are required to enter into a rebate agreement with the Secretary of Health and Human Services. *See* 42 U.S.C.A. § 1396r-8 (2009).

Plaintiffs' Response: Undisputed.

3. Effective January 1, 1991, Sandoz entered into such a rebate agreement with the Secretary of Health and Human Services. See Rebate Agreement Between The Secretary of Health and Human Services and Sandoz Inc. date stamped March 5, 1991 (hereinafter the "Rebate Agreement"), attached to the Declaration of Catherine Castaldo (hereinafter "Castaldo Decl.") as Ex. A. The Rebate Agreement remained in effect and did not substantially change from January 1, 1994 to December 31, 2004 (the "Relevant Time Period").

Plaintiffs' Response: Undisputed that Exhibit A is a Rebate Agreement date stamped March 5, 1991. Plaintiffs dispute the balance of this Statement as Defendant has presented no evidence to support its statement that the Rebate Agreement remained in effect and did not substantially change from January 1, 1994 to December 31, 2004.

4. The Rebate Agreement required Sandoz to, among other things, furnish certain information to the Secretary of Health and Human Services, including data regarding Average Manufacturer Price ("AMP"). *See* Castaldo Decl. Ex. A. at II(e).

Plaintiffs' Response: Undisputed.

5. The Rebate Agreement defines AMP as "the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail class of trade." *See* Castaldo Decl. Ex. A. at I(a).

Plaintiffs' Response: Undisputed.

6. The Rebate Agreement states that AMP "includes cash discounts allowed and all other price reductions." *See* Castaldo Decl. Ex. A at I(a).

Plaintiffs' Response: Undisputed.

7. The State of California considered AMP to be a more accurate reflection of transaction prices for drugs than Average Wholesale Price ("AWP") and other pricing indicators.

Castaldo Decl. Ex. B. (Transcript of Deposition of Mike Namba ("Namba Tr.") 150:5-10, Apr. 23, 2009)

Q: Now, have – would you agree that Average Manufacturer Price more closely approximates Average Acquisition Cost as compared to AWP?

A: I believe so.

Castaldo Decl. Ex. C. (Transcript of Deposition of Vic Walker (“Walker Tr.”) 161:22162:4, May 21, 2009).

Q: Okay. Would you consider AMP to be a better estimate of acquisition cost?

A: Better than what?

Q: AWP?

A: Probably.

Castaldo Decl. Ex. D. (Transcript of Deposition of Roy Takeuchi (“Takeuchi Tr.”) 146:2– 13, June 10, 2009).

Q: Okay. And is that consistent with your understanding that AMP was a more accurate price?

A: Is it a more accurate pricing? Well, I always thought that. I’m not really sure. I think that’s what it was.

Q: In your mind AMP was a more accurate price than other prices available?

A: I think that’s what was considered, yes.

Plaintiffs’ Response: Disputed. Vague and confusing as to time. This Court has already addressed this issue at length and found AMPs to have been confidential and “not to be revealed to third parties.” *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 152 (D. Mass. 2008). Moreover, Mr. Namba and Mr. Takeuchi are long-retired, and Mr. Walker does not occupy a policy position within Medi-Cal. “The non-public or informal understandings of agency officials concerning the meaning of a regulation are [] not relevant.” *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. Mass. 2004). The testimony cited does not support the statement that “the State of California considered AMP to be a more accurate reflection of transaction prices for drugs than Average Wholesale Price (“AWP”) and other pricing indicators.” (*See infra*, Plaintiffs’ Statement of Additional Undisputed Facts in Opposition to Sandoz, Inc.’s Motion for Summary Judgment (“CA SOAF Sandoz”) ¶ 7.)

8. Pursuant to its obligations under the Rebate Agreement, the Secretary of Health and Human Services, through CMS, is required to provide participating State Medicaid Agencies, including California, Unit Rebate Amounts (URA), which the states then use to invoice manufacturers for the rebates owed. *See* 42 U.S.C.A. § 1396r-8 (2009); Castaldo Decl. Ex. E. (Letter from Lori A. Ahlstrand, Regional Inspector for Audit Services, Dept. of Health and Human Services to Diane Bonta, Director, California Dept. of Health Services, enclosing 2003 Office of Inspector General Report: Audit of the Medicaid Drug Rebate Program in California, dated Dec. 23, 2003 (CAAG/DHS-E0032592 – E0032610)); *see also*

Castaldo Decl. Ex. F. (Transcript of Deposition of Kevin Gorospe (“Gorospe Tr.”), 713:16 – 714:11, Sept. 22, 2008)

Q: Okay. And correct me if I’m wrong, but every quarter CMS or HCFA, when HCFA was the name of the agency, sends Medi-Cal a list of what’s called the unit rebate amount for each drug that California reimbursed for; isn’t that right?

A: Specifically they send a file with a unit rebate amounts for all NDCs as reported to them by manufacturers, whether or not California reimbursed the product.

Q: Oh, okay. And do you have access to that entire list?

A: Yes. Q: Okay. So whether or not were reimbursed for a particular drug, you can actually look at the URA for that drug?

A: If it was reported by the manufacturer, correct.

Castaldo Decl. Ex. G. (Transcript of Deposition of Deidre Duzor (“Duzor Tr.”), 674:14-22, Mar. 26, 2008)

Q Okay. CMS calculates the URA and it sends the URA to all the states, right?

A: Yes.

Q: And each state gets URAs for all the drugs that it reimburses for?

A: Yes.

Q: And it gets those URAs, again, by NDC number?

A: Yes.

Plaintiffs’ Response: Undisputed as to the quoted sections of the transcripts. Disputed as to the statement that “the states then use [the URAs] to invoice manufacturers for the rebates owed.” (*See* Declaration of Steven U. Ross in Support of Plaintiffs’ Opposition to Defendant

Sandoz, Inc.'s Motion for Summary Judgment (hereinafter, "Ross Decl.") Ex. 1 (9/23/08 Douglas Hillblom Dep.) at 351:16-353:15 (manufacturers could change their URAs after receipt by California).)

9. From January 1, 1991 to December 31, 1993, URAs were set at 10% of AMP. From January 1, 1994 onwards, URAs were set at 11% of AMP. See 42 U.S.C. § 1396r-8(c)(3)(B)(2009). To calculate AMP from URA, one simply had to divide the URA amount by .1 (from 1991 to 1993) and .11 (from 1994 onwards); see also

Castaldo Decl. Ex. H. (Transcript of Deposition of Larry Reed ("Reed Tr."), 1319:6 – 1321:3, Oct. 2, 2008)

Q: Okay, so in '91, '92, '93 they are getting URAs that at 10 percent of the AMP, correct?

A: Correct.

Q: So the state Medicaid person who got URAs during that time period could look at that URA and pretty much know exactly what the AMP is just by moving the decimal point one place, correct?

Q: True?

A: There would be a way to figure – probably a way – 10 percent would be 10 percent of AMP, so basically that's correct.

Q: So really it's not much of a calculation, you just have to move the decimal point, right?

A: It would be 10 percent.

Q: It would be a pretty easy calculation, correct?

A: Again, if it was 10 percent it would be 10 times that amount.

Q: Now, the next year it went to 11 percent, correct?

A: In the calendar year 1994.

Q: And it's been at 11 percent ever since, correct?

A: Correct.

Q: So again, anyone in the state Medicaid office who gets the URA for – the URAs for generic drugs can, by doing a simple mathematical computation based on 11 percent, pretty readily determine what the AMP is, correct?

A: Correct.

Castaldo Decl. Ex. G. (Duzor Tr. at 679:12-21)

Q: Okay. So if you had the URA and you divided by .11, that would tell you what the AMP is, right? A: Yes.

The AMPs have been fairly transparent for generic drugs. Q. If you have the URA?

A: Because – right, because of the simple formula.”

Plaintiffs’ Response: Undisputed as to the calculation for noninnovator generic drugs.

Disputed as to generic drugs on which innovator rebates were paid (including the Sandoz drugs Bromocriptine, Glyburide, Methylphenidate and Nitrofurantoin MCR).

10. Armed with URAs, the State of California can easily determine the AMP for a given drug.

Castaldo Decl. Ex. I. (Transcript of Deposition of Kevin Gorospe (“Gorospe Tr.”), 77:9-16, Mar. 19, 2008)

Q. So it if was ten percent -- if the rebate was ten percent of AMP and you -- all you would have to do is sort of, you know, use simple division to figure out what the AMP was based on the unit rebate amount?

A: Correct.

Castaldo Decl. Ex. J. (Transcript of Deposition of Craig Miller (“Miller Tr.”), 83:15 – 84:8 Sept. 24, 2008)

Q: But that's something you could fairly -- at least for the noninnovator multiple source drugs we talked about a few minutes ago, that's something that if I -- if you wanted to you could figure that AMP number relatively simply; couldn't you? ...

A: Oh. Yes.

Q: I mean you just do the math?

A: Right.

Q: You reverse that division –

A: Right.

Q: -- with a calculator, and you’ve got the AMP?

A: Right.

Castaldo Decl. Ex. K. (Transcript of Deposition for Douglas Hillblom (“Hillblom Tr.”) 264: 17-19, Sept. 23, 2008)

Q: How would you derive AMP from URA?

A: You'd have to take the URA amount and divide it by the appropriate percentage, and multiply it by a hundred.

Plaintiffs' Response: Disputed. Manufacturers have the ability to change the URAs provided to California. (*See* Ross Ex. 1 (9/23/08 Douglas Hillblom Dep.) at 351:16-353:15.) In addition, Plaintiff could not “easily” determine the AMP for innovator generic drugs.

11. The State of California has used URA information to calculate manufacturers' AMP data.

Castaldo Decl. Ex. B. (Namba Tr. at 165:14-166:5)

Q: And what information did you have about the – in connection with the CMS rebate? Is this – did you have AMPs, or did you have URAs? Do you recall?

A: Yes. If the manufacturer had contacted us and was interested in pursuing additional formulary, they'd give us AMP. That was the requirement. So we had it. But we could also calculate from the CMS information that we had, because our rebate was set at 11 percent fixed.

Castaldo Decl. Ex. B. (Namba Tr. at 166:16 – 167:3)

Q: Okay. But ... you just noted that you could find – from the unit rebate amount you could – you could calculate the – what the AMP would be?

A: For generic drugs.

Q: For generic drugs right. And so you saw, when you calculated AMP for the generic drug, that it – it was a very low number; right?

A: Correct.

Plaintiffs' Response: Disputed. The testimony cited by Defendant does not support the statement that California used URA information to calculate manufacturers' AMP data. (*See* CA SOAF Sandoz, ¶ 4 (California did not calculate AMPs from URAs); Ross Ex. 2 (10/22/08 Craig Miller Dep.) at 234:6-22.)

12. Notwithstanding its obligations to provide AMP data to the federal government pursuant to the Rebate Agreement, beginning on July 16, 1991, Sandoz voluntarily provided the State of California with its AMP data. *See* Castaldo Decl. Ex. L. (Letter from Beth Brannan, Manager, Government Affairs, Geneva Pharmaceuticals, Inc. (Sandoz) to Michael Neff, California Dept. of Health Services enclosing AMP data, dated July 16, 1991 (SANDOZ CALI 3000033)); *see also*

Castaldo Decl. Ex. D. (Takeuchi Tr. at 145:3 -22)

Q: Mr. Takeuchi, -- based on Exhibit 17 through 19 would you agree with me that California received Sandoz' AMPs for its products reimbursed by California.

A: Just what I see, it looks like it.

Q: Okay.

A: I don't know if that's everything.

Q: But California did receive AMPs for at least some products from Geneva from 1992 through 1996; correct?

A: If -- if the mailing and everything else was correct, looks like it.

Plaintiffs' Response: Undisputed that Defendant provided AMP data to California on or about July 16, 1991. Vague and confusing thereafter as to time. Disputed that Defendant *voluntarily* provided such data. (See CA SOAF Sandoz ¶ 1 (From 1991 through 1996 California required each drug manufacturer whose products were on the Medi-Cal formulary, including Defendant Sandoz, Inc., to provide California with AMP data in connection with supplemental rebate contracts entered into between California and each drug manufacturer, including Defendant Sandoz, Inc.); Ross Ex. 3 (4/23/09 Mike Namba Dep.) at 155:4-8.)

13. Sandoz continued to directly provide the State of California with its AMP data until March 21, 1997. See Castaldo Decl. Ex. M. (Letter from Ron Hartmann, Manager, Government Affairs, Geneva Pharmaceuticals, Inc. (Sandoz) to State of California enclosing AMP data, dated Mar. 21, 2007 (SANDOZ CALI 3001109)).

Plaintiffs' Response: Disputed. Although Sandoz may have transmitted AMP data in 1997, the AMP data referred to periods in 1996, pursuant to the supplemental rebate agreement between Plaintiff and Sandoz. (See CA SOAF Sandoz ¶ 1 (From 1991 through 1996 California required each drug manufacturer whose products were on the Medi-Cal formulary, including Defendant Sandoz, Inc., to provide California with AMP data in connection with supplemental rebate contracts entered into between California and each drug manufacturer, including Defendant Sandoz, Inc.); Ross Ex. 3 (4/23/09 Mike Namba Dep.) at 155:4-8.)



**PLAINTIFFS' SEPARATE STATEMENT OF ADDITIONAL UNDISPUTED FACTS IN  
OPPOSITION TO SANDOZ INC.'S MOTION FOR SUMMARY JUDGMENT**

1. From 1991 through 1996 California required each drug manufacturer whose products were on the Medi-Cal formulary, including Defendant Sandoz, Inc., to provide California with AMP data in connection with supplemental rebate contracts entered into between California and each drug manufacturer, including Defendant Sandoz, Inc. (Ross Ex. 3 (4/23/09 Mike Namba Dep.) at 155:4-8.)

2. The AMP data that California received from the drug manufacturers was given to the EDS drug rebate unit to validate that the format was followed and that there were no errors, and was then turned over to the EDS system's group who would load the data into the system to calculate the supplemental rebates. (Ross Ex. 4 (10/21/08 Maureen Tooker Dep.) at 17:21-18:22.)

3. California used the AMP data received from drug manufacturers for the calculation of supplemental rebates only. (Ross Ex. 2 (10/22/08 Craig Miller Dep.) at 320:10-321:4.)

4. California did not calculate AMPs from URAs. (Ross Ex. 2 (10/22/08 Craig Miller Dep.) at 234:6-22.) Manufacturers could and did change or restate the AMPs which they previously provided to California, causing AMP data to be unreliable. (Ross Ex. 12 (3/19/08 Kevin Gorospe Dep.) at 373:6-18, 374:8-375:10.)

5. Unless California law allowed for the use of AMPs as a basis for reimbursement, California did not use AMPs in connection with discussions about reimbursement or policy decisions concerning reimbursement. (Ross Ex. 5 (9/22/08 J. Kevin Gorospe Dep.) at 671:11-19; Ross Ex. 1 (9/23/08 Douglas B. Hillblom Dep.) at 265:10-266:6.)

6. California did not use URAs in connection with discussions about reimbursement or policy decisions concerning reimbursement. (Ross Ex. 1 (9/23/08 Douglas B. Hillblom Dep.) at 265:10-266:6.)

7. California did not compare AMPs or URAs with any other pricing information, including AWP. (Ross Ex. 2 (10/22/08 Craig Miller Dep.) at 316:18-319:16.)

8. California has always treated AMP data as confidential under federal law. (Ross Ex. 6 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 283:14-284:3.)

9. California believed that using AMP data to establish a reimbursement formula would breach the confidentiality afforded to AMPs under federal law. (Ross Ex. 6 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 284:15-285:8.)

10. In May 2007, a representative of Defendant Mylan met with Dr. Kevin Gorospe, Chief of the Medi-Cal Pharmacy Policy Unit at the California Department of Health Care Services. The meeting included a discussion about AMPs in which the Mylan representative described AMPs as a poor basis for reimbursement because they were unreliable. (Ross Ex. 5 (9/22/08 J. Kevin Gorospe Dep.), at 693:7-694:5.)

11. At the meeting in May 2007, the Mylan representative presented Dr. Gorospe with a report prepared by GPhA which stated that AMPs were inappropriate for use as the basis for pharmacy reimbursement for a variety of reasons. (Ross Ex. 5 (9/22/08 J. Kevin Gorospe Dep.) at 654:14-657:7.)

12. In October 2005 GPhA sent a letter to Charles Grassley, Chairman, Committee on Finance, and to Max Baucus, Ranking Member, Committee on Finance for the purpose of cautioning the United States Senate Committee on Finance about using AMPs as a basis to

calculate pharmacy reimbursement, as AMPs did not represent an accurate reflection of true market prices. (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 75:18-77:17, referring to Ex. 57.)

13. In February 2007 GPhA sent a letter to the Centers for Medicare & Medicaid Services (“CMS”) advising CMS that AMPs are easily misinterpreted “when payers, state agencies and consumers rely on AMPs to indicate actual prices available in the marketplace.” (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 78:15-80:8, referring to Ex. 58.)

14. In 2005 GPhA created the Medicaid Task Force (also called the AMP Task Force) in response to the proposed federal Deficit Reduction Act. The purpose of the Medicaid Task Force was to address the concerns of the generic pharmaceutical industry about AMPs. As of 2007 Defendant Sandoz was a member of the Medicaid Task Force. (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 55:9-56:11.)

15. In 2007 attorneys for GPhA prepared a “white paper” for California, the purpose of which was to explain the position of GPhA that AMPs were not an adequate basis upon which to calculate pharmacy reimbursement, to talk about the limitations of AMPs and to express concerns about the confidentiality of AMPs. (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 39:12-41:18, referring to Ex. 53.)

16. Prior to the GPhA white paper being sent to California, it was reviewed by members of the GPhA State Government Affairs Committee. Defendant Sandoz, Inc. was a member of that committee. (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 42:1-19, referring to Ex. 53.)

17. In its white paper sent to California, GPhA talked about the fluctuations of AMPs and why AMPs would be unreliable data points to try to calculate pharmacy reimbursement. The white paper further set out the positions of GPhA that AMPs are mistakenly perceived as indicators of market prices, and that AMPs bear little relevance to market prices. None of GPhA's members, including Defendant Sandoz, Inc., disagreed with these positions. (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 45:6-51:14, referring to Ex. 53.)

18. According to GPhA, using AMPs would not be an accurate way of calculating the price charged by a manufacturer to consumers. (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 51:20-52:19, 98:8-14.)

19. A representative from Sandoz, Inc. (traditionally the CEO) has always sat on the Board of Directors of GPhA, and the GPhA Executive Committee. (Ross Ex. 8 (5/6/09 Rule 30(b)(6) Sandoz, Inc. (Hartmann) Dep.) at 370:19-371:17.)

20. Sandoz, Inc. was a member of GPhA's Medicaid Task Force. (Ross Ex. 8 (5/6/09 Rule 30(b)(6) Sandoz, Inc. (Hartmann) Dep.) at 372:7-13.)

21. Sandoz, Inc. agreed with the position taken by GPhA that "AMP is mistakenly perceived as an indicator of market prices, however, it bears little relevance to market price." (Ross Ex. 8 (5/6/09 Rule 30(b)(6) Sandoz, Inc. (Hartmann) Dep.) at 398:13-399:11.)

22. Sandoz, Inc. never explained to anyone at California's Department of Health Services the difference between provider actual acquisition costs for its drugs and its reported AWP. (Ross Ex. 9 (11/6/08 CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 302:8-15; Ross Ex. 5 (9/22/08 Kevin Gorospe Dep.), at 698:14-19.)

23. It has never been the policy of California's Medi-Cal program to deliberately accept inflated and inaccurate AWP's because the program knew this would offset low dispensing fees to pharmacists. (Ross Ex. 9 (11/6/08 CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 313:10-19.)

24. Sandoz, Inc. did not report its transactional prices, nor any average or compilation of these prices, to the pricing compendia or to Medi-Cal as its products' AWP's or otherwise. (Ross Ex. 10 (1/27/09 Frank Stiefel Dep.) at 379:19-380:7.)

25. There was no fixed or predictable relationship between the AWP's that Sandoz, Inc. reported to FDB and the prices at which its products were sold to the retail class of trade. (Ross Ex. 11 (6/11/07 Kevin Galownia Dep.) at 169:5-17.)

26. Sandoz, Inc. was aware of or on notice that Medi-Cal reimbursed providers for pharmaceutical products based on the reported AWP's of its products. (Ross Ex. 8 (5/6/09 Rule 30(b)(6) Sandoz, Inc. (Hartmann) Dep.) at 330:21-332:14.)

Dated: December 21, 2009

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 21, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Steven U. Ross  
STEVEN U. ROSS